

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services amends Chapter 77, “Conditions of Participation for Providers of Medical and Remedial Care,” Iowa Administrative Code.

These amendments affect the provider standards for home- and community-based habilitation services and for the seven home- and community-based services (HCBS) waivers (ill and handicapped, elderly, AIDS/HIV, mental retardation, brain injury, physical disability, and children’s mental health). The Centers for Medicare and Medicaid Services (CMS) has approved amendments to Iowa’s waivers that require a process for incident reporting. The changes are required by CMS and must be implemented for Iowa to continue to receive federal financial participation for home- and community-based services.

The amendments:

- Amend the incident reporting standards for habilitation providers and service providers under the mental retardation, brain injury, and children’s mental health waivers.
- Add identical incident reporting standards for providers of services under the ill and handicapped, elderly, AIDS/HIV, and physical disability waivers.

The incident reporting standards apply only to providers who have personal contact with members. The standards define “major” and “minor” incidents, prescribe the content of the incident report form, and set procedures for reporting of major and minor incidents. Minor incidents will be reported only internally to the provider supervisor and noted in the member’s file. Major incidents will also be reported to the member or the member’s guardian, the member’s case manager, and the Department’s Bureau of Long-Term Care, using a report form prescribed by the Department. Providers will be required to track and analyze incidents to determine if further training or changes in service procedures are needed.

These amendments exempt providers without direct member contact from the new incident reporting requirements. Otherwise, these amendments do not provide for waivers in specified situations because all providers that have direct contact with members should be held to the same standards of protection. Providers or members may request a waiver of any rule under the Department’s general rule on exceptions at rule 441—1.8(17A,217).

Notice of Intended Action on these amendments was published in the Iowa Administrative Bulletin on March 25, 2009, as **ARC 7653B**. The Department received comments on the Notice of Intended Action from 13 people. In response to these comments, the Department has made the following changes to the amendments published under Notice of Intended Action:

- Changed the wording of numbered paragraph “7” in the definition of “Major incident” to read “Involves a member’s location being unknown by provider staff who are assigned protective oversight.” The change is intended to clarify that the rule does not require each provider to know the member’s location at all times. This definition occurs in subrule 77.25(1) and paragraphs 77.30(18)“a,” 77.33(22)“a,” 77.34(14)“a,” 77.37(8)“a,” 77.39(6)“a,” and 77.41(12)“a,” and in subparagraph 77.46(1)“d”(1).
- Extended the time for reporting minor incidents from 24 hours to 72 hours and clarified that the provider may designate the format for reporting minor incidents. This change is reflected in paragraphs 77.25(3)“a,” 77.30(18)“b,” 77.33(22)“b,” 77.34(14)“b,” 77.37(8)“b,” 77.39(6)“b,” and 77.41(12)“b” and in subparagraph 77.46(1)“d”(2).
- Revised the procedures for reporting major incidents. The revised amendments clarify that notification to the member or consumer is required only if the incident took place outside of the reporting provider’s service provision and extend the time for filing the initial incident report from 24 hours to the end of the next calendar day. Information has been added about the automated process that will be available for incident reporting and the follow-up to the report by the case manager. The title of the printed report form is changed to “Critical Incident Report.” These changes are reflected

in paragraphs 77.25(3)“b,” 77.30(18)“c,” 77.33(22)“c,” 77.34(14)“c,” 77.37(8)“c,” 77.39(6)“c,” and 77.41(12)“c” and in subparagraphs 77.46(1)“d”(3) through (6).

The Council on Human Services adopted these amendments on June 10, 2009.

These amendments are intended to implement Iowa Code section 249A.4.

These amendments shall become effective on September 1, 2009.

The following amendments are adopted.

ITEM 1. Rescind the definition of “Incident” in subrule **77.25(1)**.

ITEM 2. Adopt the following new definitions in subrule **77.25(1)**:

“*Major incident*” means an occurrence involving a member during service provision that:

1. Results in a physical injury to or by the member that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the member;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a member’s location being unknown by provider staff who are assigned protective oversight.

“*Member*” means a person who has been determined to be eligible for Medicaid under 441—Chapter 75.

“*Minor incident*” means an occurrence involving a member during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

ITEM 3. Rescind subrule 77.25(3) and adopt the following new subrule in lieu thereof:

77.25(3) *Incident management and reporting.* As a condition of participation in the medical assistance program, HCBS habilitation service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule.

a. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the member’s file.

b. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The member or the member’s legal guardian. EXCEPTION: Notification to the member is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The member’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the member involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other members or nonmembers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the member's file.

c. *Tracking and analysis.* The provider shall track incident data and analyze trends to assess the health and safety of members served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 4. Amend rule 441—77.30(249A), introductory paragraph, as follows:

441—77.30(249A) HCBS ill and handicapped waiver service providers. HCBS ill and handicapped waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A provider hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS ill and handicapped waiver program if they meet the standards in subrule 77.30(18) and also meet the standards set forth below for the service to be provided:

ITEM 5. Adopt the following **new** subrule 77.30(18):

77.30(18) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS ill and handicapped waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, home-delivered meals, or personal emergency response.

a. *Definitions.*

“*Major incident*” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;

5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;

6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or

7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.

3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.

5. The action that the provider staff took to manage the incident.

6. The resolution of or follow-up to the incident.

7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

d. *Tracking and analysis.* The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 6. Amend rule 441—77.33(249A), introductory paragraph, as follows:

441—77.33(249A) HCBS elderly waiver service providers. HCBS elderly waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS elderly waiver program if they meet the standards in subrule 77.33(22) and also meet the standards set forth below for the service to be provided:

ITEM 7. Adopt the following **new** subrule 77.33(22):

77.33(22) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS elderly waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of assistive devices, chore service, goods and services purchased under the consumer choices option, home and vehicle modification, home-delivered meals, personal emergency response, or transportation.

a. *Definitions.*

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“Minor incident” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member's supervisor.
2. The consumer or the consumer's legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.

3. The consumer's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 8. Amend rule 441—77.34(249A), introductory paragraph, as follows:

441—77.34(249A) HCBS AIDS/HIV waiver service providers. HCBS AIDS/HIV waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS AIDS/HIV waiver program if they meet the standards in subrule 77.34(14) and also meet the standards set forth below for the service to be provided:

ITEM 9. Adopt the following new subrule 77.34(14):

77.34(14) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS AIDS/HIV waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The

conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or to home-delivered meals.

a. Definitions.

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“Minor incident” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.

7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 10. Amend rule **441—77.37(249A)**, first unnumbered paragraph, as follows:

The standards in subrule 77.37(1) apply only to providers of supported employment, respite providers certified according to subparagraph 77.37(15) "a"(8), and providers of supported community living services that are not residential-based. The standards and certification processes in subrules 77.37(2) through 77.37(7) and 77.37(9) through 77.37(12) apply only to supported employment providers and non-residential-based supported community living providers.

ITEM 11. Rescind subrule 77.37(8) and adopt the following **new** subrule in lieu thereof:

77.37(8) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS mental retardation waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, personal emergency response, and transportation.

a. Definitions.

"Major incident" means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph "1," "2," or "3"; or
7. Involves a consumer's location being unknown by provider staff who are assigned protective oversight.

"Minor incident" means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member's supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff consumer's supervisor.
2. The consumer or the consumer's legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.

3. The consumer's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 12. Rescind subrule 77.39(6) and adopt the following **new** subrule in lieu thereof:

77.39(6) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS brain injury waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, personal emergency response, and transportation.

a. Definitions.

"Major incident" means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;

6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or

7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

d. *Tracking and analysis.* The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 13. Adopt the following **new** subrule 77.41(12):

77.41(12) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS physical disability waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, specialized medical equipment, personal emergency response, and transportation.

a. Definitions.

“*Major incident*” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.

4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.

5. The action that the provider staff took to manage the incident.

6. The resolution of or follow-up to the incident.

7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

ITEM 14. Rescind paragraph 77.46(1)“d” and adopt the following **new** paragraph in lieu thereof:

d. Incident management and reporting. As a condition of participation in the medical assistance program, HCBS children's mental health waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and must comply with the following incident management and reporting requirements. EXCEPTION: The conditions in this paragraph do not apply to providers of environmental modifications and adaptive devices.

(1) Definitions.

“*Major incident*” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;

2. Results in the death of any person;

3. Requires emergency mental health treatment for the consumer;

4. Requires the intervention of law enforcement;

5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;

6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or

7. Involves a consumer's location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;

2. Results in bruising;

3. Results in seizure activity;

4. Results in injury to self, to others, or to property; or

5. Constitutes a prescription medication error.

(2) Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member's supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

(3) Notification procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident, the staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member's supervisor.
2. The consumer or the consumer's legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.
3. The consumer's case manager.
- (4) Reporting procedure for major incidents. By the end of the next calendar day after a major incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:
 1. By direct data entry into the Iowa Medicaid Provider Access System, or
 2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.
- (5) Information to be reported. The following information shall be reported about a major incident:
 1. The name of the consumer involved.
 2. The date and time the incident occurred.
 3. A description of the incident.
 4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
 5. The action that the provider staff took to manage the incident.
 6. The resolution of or follow-up to the incident.
 7. The date the report is made and the handwritten or electronic signature of the person making the report.
- (6) Response to report. Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about a major incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.
- (7) Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

[Filed 6/12/09, effective 9/1/09]

[Published 7/1/09]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 7/1/09.